



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

GE Vingmed Ultrasound AS  
% Mr. Bryan Behn  
Regulatory Affairs Manager  
GE Healthcare  
9900 W Innovation Drive, RP-2138  
WAUWATOSA WI 53226

March 2, 2015

Re: K150085  
Trade/Device Name: EchoPAC  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: January 14, 2015  
Received: January 15, 2015

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. A large, faint "FDA" watermark is visible in the background behind the signature.

Robert Ochs, Ph.D.  
Acting Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150085

Device Name

EchoPAC

### Indications for Use (Describe)

The GE EchoPAC is indicated for diagnostic review and analysis of ultrasound images acquired via B (2D), M, Color M modes, Color, Power, Pulsed and CW Doppler modes, Coded Pulse, Harmonic and Real time 3D. Clinical applications include: Fetal; Abdominal (including renal and GYN) ; Urology (including prostate); Pediatric; Small organs (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Transesophageal (TEE); Musculo-skeletal Conventional; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic and vascular).

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**GE Healthcare**  
510(k) Premarket Notification Submission

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Section 5: 510(k) Summary

GE EchoPAC

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## GE Healthcare

### 510(k) Premarket Notification Submission

#### 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: January 14, 2015

Submitter: GE Healthcare  
9900 Innovation Dr  
Wauwatosa, WI 53226

Primary Contact Person: Bryan Behn  
Regulatory Affairs Manager  
GE Healthcare  
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Secondary Contact Person: Charlotte Kaas Munthe Jørgensen  
Regulatory Affairs Specialist  
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Device: Trade Name: GE EchoPAC Workstation Software for ultrasound image review, analysis and reporting

Common/Usual Name: EchoPAC

Classification Names: Class II

Product Code: 21 CFR 892.2050

Predicate Device(s): K131685 GE EchoPAC  
K142323 Vivid S60/S70

Device Description: GE EchoPAC provides image processing, annotation, analysis, measurement, report generation, communication, storage and retrieval of ultrasound images that are acquired via GE Vivid family of ultrasound scanners, primarily for cardiology ultrasound applications but also for general imaging. The EchoPAC software is an integral component of each Vivid system, providing the post-acquisition image management and reporting functions of the scanner. EchoPAC will be offered as SW-only to be installed directly on customer PC hardware, or as an accessory to selected 3rd party image management workstations. EchoPAC is DICOM compliant, transferring images and data via LAN between scanners, hard copy devices, file servers and other workstations. The modified or added software features for GE EchoPAC are substantially equivalent to the predicate device and functionality cleared on GE EchoPAC K131685

Intended Use: The GE EchoPAC Software Only is indicated for diagnostic review and analysis of ultrasound images acquired via B (2D), M, Color M modes, Color, Power, Pulsed and CW Doppler modes,



## GE Healthcare

### 510(k) Premarket Notification Submission

Coded Pulse, Harmonic and Real time 3D. Clinical applications include: Fetal; Abdominal (including renal and GYN) ; Urology (including prostate); Pediatric; Small organs (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Transesophageal (TEE); Musculo-skeletal Conventional; Transrectal (TR); Transvaginal (TV); and Intraoperative (abdominal, thoracic and vascular).

Technology: The GE EchoPAC employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence: The GE EchoPAC systems are substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

	Proposed Device GE EchoPAC	Predicate Device GE EchoPAC (K131685 )
Indications and Clinical Applications:		
• Fetal;	✓	✓
• Abdominal (Including Renal & Gyn)	✓	✓
• Urology (including prostate);	✓	✓
• Pediatric	✓	✓
• Small Organ (breast, testes, thyroid);	✓	✓
• Neonatal and Adult Cephalic;	✓	✓
• Cardiac (adult and pediatrics);	✓	✓
• Peripheral Vascular;	✓	✓
• Transesophageal (TEE);	✓	✓
• Musculo-skeletal Conventional	✓	✓
• Transrectal (TR);	✓	✓
• Transvaginal (TV);	✓	✓
• Intraoperative (abdominal, thoracic, & vascular).	✓	✓
Image modes:  B (2D), M, Color M modes, Color, Power, Pulsed and CW Doppler modes, Coded Pulse, Harmonic and Real time 3D	✓	✓



# GE Healthcare

## 510(k) Premarket Notification Submission

<p>Processing &amp; Display features:</p> <p>Image mapping (color &amp; gray), Time/ spatial filtering and enhancement, TGC, TVI, SI/SRI, TSI, Harmonic Imaging, Pulsatile-Flow, B-Flow, Extended FOV, Tissue Tracking, Realtime 3D and Multi-plane processing, 2D Stress and Multiplane Stress, 4D Stress, TSI w/ surface rendering, Blood Flow Imaging (BFI), Spatial Compounding / Speckle Reduction imaging, LCD display, Realtime 3D Color Flow, Automated Functional Imaging (AFI), Triplane AFI, Auto EF (2D), Depth Color Rendering/map, Depth Illumination map, Stereo Vision (Anaglyph Stereo Vision and Polarized Stereo Vision), 2 Click Crop, FlexiSlice, LaserLines, Auto ROI,</p> <p>HD live,</p> <p>AFI Stress.</p>	<p>✓</p> <p>✓</p> <p>✓</p> <p>(Improvement to Depth Illumination Map)</p> <p>✓</p> <p>(same features as on the predicate Vivid S60/S70 K142323)</p>	<p>✓</p>
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<p>Measurement &amp; Analysis</p> <p>Length, Area, Time, Circumference, Volume, Heart rate, Slope, Velocity, Angle, Thickness Measurement Tool (IMT), OB Tables, Vascular and Cardiac calcs. including Strain (2D and 4D) and Strain rate, 4D LV Function by TomTec, 4D RV Function by TomTec, 4D LV Mass, Mitral Valve (MV) Quantification tool by TomTec, Z-score, LA Volume by Biplane Simpson, 4D Auto LVQ, Multilayered 2D Strain , ROI width adjustment, Time Caliper, Export of 4D Strain trace and mesh data,</p> <p>4D Auto AVQ.</p>	<p>✓</p> <p>✓</p> <p>✓</p> <p>(modification of area measurements used in predicate EchoPAC)</p>	<p>✓</p>
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The GE EchoPAC and its applications comply with voluntary standards. The following quality assurance measures were applied to the development of the system:

- 5-5



## GE Healthcare

### 510(k) Premarket Notification Submission

The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

#### Summary of Clinical Tests:

The subject of this premarket submission, GE EchoPAC, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the GE EchoPAC to be as safe, as effective, and performance is substantially equivalent to the predicate devices.